

**UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF WEST VIRGINIA  
CHARLESTON DIVISION**

**IN RE: BOSTON SCIENTIFIC CORP.,  
PELVIC REPAIR SYSTEM  
PRODUCTS LIABILITY LITIGATION**

**MDL No. 2326**

**THIS DOCUMENT RELATES TO THE FOLLOWING CASES:**

ADAMS, Ida vs. BOSTON SCIENTIFIC CORP., 17-cv-02588  
ALLEN, Kimberly vs. BOSTON SCIENTIFIC CORP., 17-cv-01837  
ALLEX, Dominique vs. BOSTON SCIENTIFIC CORP., 17-cv-02443  
ALVARADO, Perla vs. BOSTON SCIENTIFIC CORP., 17-cv-02243  
ATWOOD, Jennifer vs. BOSTON SCIENTIFIC CORP., 17-cv-02202  
BABCOCK, Christine vs. BOSTON SCIENTIFIC CORP., 17-cv-00701  
BARNETT, Cheryl vs. BOSTON SCIENTIFIC CORP., 17-cv-02589  
BENSON, Angela vs. BOSTON SCIENTIFIC CORP., 17-cv-01996  
BLACK, Roberta vs. BOSTON SCIENTIFIC CORP., 17-cv-02730  
BLALOCK, Laceta vs. BOSTON SCIENTIFIC CORP., 17-cv-02446  
BROWN, Tracy vs. BOSTON SCIENTIFIC CORP., 17-cv-01243  
BUSBY, Amy vs. BOSTON SCIENTIFIC CORP., 17-cv-02111  
BUTTKE, Louise vs. BOSTON SCIENTIFIC CORP., 17-cv-02638  
CASALE, Claire vs. BOSTON SCIENTIFIC CORP., 17-cv-02447  
CHILDRESS, Carolyn, vs. BOSTON SCIENTIFIC CORP., 17-cv-02590  
CLARK, June vs. BOSTON SCIENTIFIC CORP., 17-cv-02448  
CLARK, Sandra vs. BOSTON SCIENTIFIC CORP., 17-cv-02110  
COLE, Bonnie vs. BOSTON SCIENTIFIC CORP., 17-cv-02449  
CONLEY, Jaime vs. BOSTON SCIENTIFIC CORP., 17-cv-01940  
CUTLIP, Lisa G. vs. BOSTON SCIENTIFIC CORP., 17-cv-02505  
DANIELL, Edwina vs. BOSTON SCIENTIFIC CORP., 17-cv-02486  
DEMBSKI, Linda vs. BOSTON SCIENTIFIC CORP., 17-cv-01074  
DICKESON, Penny vs. BOSTON SCIENTIFIC CORP., 17-cv-02592  
DUNFORD, Glenda and Delbert Dunford vs. BOSTON SCIENTIFIC CORP., 17-cv-01979  
EVANS, Bonnie vs. BOSTON SCIENTIFIC CORP., 17-cv-01242  
FASO, Susan and Carmen Faso vs. BOSTON SCIENTIFIC CORP., 17-cv-01862  
GOTTFREID, Debra vs. BOSTON SCIENTIFIC CORP., 17-cv-02646  
GRIGG, Teresa R. vs. BOSTON SCIENTIFIC CORP., 17-cv-00294  
HARDWICK, Zena vs. BOSTON SCIENTIFIC CORP., 17-cv-01977  
HARRISON-HOOD, Amy vs. BOSTON SCIENTIFIC CORP., 17-cv-02641  
HAUFF, Anita Lynne and Frederick J. Hauff vs. BOSTON SCIENTIFIC CORP., 17-cv-01900  
HENJUM, Linda vs. BOSTON SCIENTIFIC CORP., 17-cv-02734  
JETER, Marsha Sue vs. BOSTON SCIENTIFIC CORP., 17-cv-02508  
LONG, Shelia vs. BOSTON SCIENTIFIC CORP., 17-cv-00047  
LOPEZ, Deann vs. BOSTON SCIENTIFIC CORP., 17-cv-01155  
LOWRIE, Tracy vs. BOSTON SCIENTIFIC CORP., 17-cv-01959  
MAHNKE, Dana vs. BOSTON SCIENTIFIC CORP., 17-cv-00568

MALLORY, Sandra vs. BOSTON SCIENTIFIC CORP., 17-cv-02459  
MARTIN, Delores Jackson vs. BOSTON SCIENTIFIC CORP., 17-cv-02738  
MARTIN, Joyce vs. BOSTON SCIENTIFIC CORP., 17-cv-02461  
MARTINEZ, Dolores vs. BOSTON SCIENTIFIC CORP., 17-cv-02739  
MASTERSON, Mary vs. BOSTON SCIENTIFIC CORP., 17-cv-02417  
MCFOLLING, Marlene vs. BOSTON SCIENTIFIC CORP., 17-cv-02596  
MCSWEEN, Belinda vs. BOSTON SCIENTIFIC CORP., 17-cv-02462  
MELROSE, Mary vs. BOSTON SCIENTIFIC CORP., 17-cv-02467  
MORALES, Geraldine vs. BOSTON SCIENTIFIC CORP., 17-cv-02742  
MORGAN, Flora vs. BOSTON SCIENTIFIC CORP., 17-cv-02597  
MURRAY, Beverly Ingrid Pamensky vs. BOSTON SCIENTIFIC CORP., 17-cv-02093  
NOTESTINE, Rhea vs. BOSTON SCIENTIFIC CORP., 17-cv-00534  
PALMER, Donna vs. BOSTON SCIENTIFIC CORP., 17-cv-02416  
PIERSON, Sherry and David Pierson, Jr. vs. BOSTON SCIENTIFIC CORP., 17-cv-02633  
PORTER, Annie vs. BOSTON SCIENTIFIC CORP., 17-cv-02470  
POUNCY, Angel vs. BOSTON SCIENTIFIC CORP., 17-cv-02477  
PRICE, Armentha vs. BOSTON SCIENTIFIC CORP., 17-cv-01939  
REID, Nancy vs. BOSTON SCIENTIFIC CORP., 17-cv-02598  
REYES, Lori vs. BOSTON SCIENTIFIC CORP., 17-cv-02599  
RINALDI, Ellen vs. BOSTON SCIENTIFIC CORP., 17-cv-02600  
ROSS, Debora vs. BOSTON SCIENTIFIC CORP., 17-cv-02107  
SCHRODER, Annette vs. BOSTON SCIENTIFIC CORP., 17-cv-01938  
SHAW, Andra vs. BOSTON SCIENTIFIC CORP., 17-cv-02745  
SHEPARD, Anne Marie vs. BOSTON SCIENTIFIC CORP., 17-cv-02481  
SHIFLET, Brenda vs. BOSTON SCIENTIFIC CORP., 17-cv-01845  
SMITH, Judy vs. BOSTON SCIENTIFIC CORP., 17-cv-02483  
SOLOMON, Pamela vs. BOSTON SCIENTIFIC CORP., 17-cv-02551  
SPEED, Margaret vs. BOSTON SCIENTIFIC CORP., 17-cv-02244  
SPENCER, Yvonne vs. BOSTON SCIENTIFIC CORP., 17-cv-02553  
STAPF, Bonnie vs. BOSTON SCIENTIFIC CORP., 17-cv-02787  
SUSTAITA, Stella vs. BOSTON SCIENTIFIC CORP., 17-cv-00528  
SUTLIFF, Amanda vs. BOSTON SCIENTIFIC CORP., 17-cv-00536  
TIGNER, Tammy vs. BOSTON SCIENTIFIC CORP., 17-cv-01241  
WALLACE, Margaret vs. BOSTON SCIENTIFIC CORP., 17-cv-02450  
WELSH, Pamela vs. BOSTON SCIENTIFIC CORP., 17-cv-02568  
WILSON, Gwendolyn vs. BOSTON SCIENTIFIC CORP., 17-cv-02106  
WITTENBORN, Evelyn vs. BOSTON SCIENTIFIC CORP., 17-cv-02571  
ZEITER, Mary vs. BOSTON SCIENTIFIC CORP., 17-cv-01098

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**RESPONSE IN OPPOSITION TO PLAINTIFFS’  
MOTION TO EXCLUDE THE OPINIONS AND TESTIMONY OF  
STEVEN R. LITTLE, Ph.D.**

Defendant Boston Scientific Corporation (“Boston Scientific”) submits the following Response in Opposition to Plaintiffs’ Motion and Memorandum of Law in Support of Their Motion to Exclude the Opinions and Testimony of Steven R. Little, Ph.D. (“Mtn. to Exclude Dr. Little ”).<sup>1</sup> Boston Scientific respectfully shows the Court as follows:

**INTRODUCTION**

Plaintiffs’ Motion to Exclude Dr. Little fails to present any valid reason to exclude Dr. Little, instead it outlines points for cross-examination while misstating the record. Dr. Little is a chemical engineer with a Ph.D. from the Massachusetts Institute of Technology and expert in polymers and biomaterials.<sup>2</sup> He is the Chairman of the Department of Chemical Engineering and an Endowed Professor of Chemical Engineering, Bioengineering, Pharmaceutical Sciences, Immunology, Ophthalmology and the McGowan Institute for Regenerative Medicine at the University of Pittsburgh. He is the Director of the Controlled Release and Biomimetic Research Laboratories overseeing millions of dollars in research and over twenty researchers. He has been recognized and received awards from the leading biomaterials societies and been published over 70 times in peer-reviewed publications on the subject of biomaterials. Plaintiffs admit that Dr. Little has “experience in the field of biomaterials including polypropylene.” Motion at 3.

In support of their Motion to Exclude Dr. Little, Plaintiffs assert the following arguments: (1) Dr. Little’s opinions regarding oxidative degradation lack a reliable basis because he has not examined mesh and (2) Dr. Little should be precluded from offering “state of mind and intent” opinions regarding the Chevron Phillips’ Medical Application Caution contained within the

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<sup>1</sup> A true and accurate copy of Dr. Little’s expert report is attached as Exhibit A.

<sup>2</sup> A true and accurate copy of Dr. Little’s CV is attached as Exhibit B.

Marlex HGX-030-01 Material Safety Data Sheet (“MSDS”). These arguments fail for several reasons.

First, Dr. Little bases his opinions on the oxidative degradation of polypropylene on his education, training, experience, and review of the relevant scientific and medical literature. This forms a reliable scientific basis for his opinions. Second, Dr. Little will not opine regarding the state of mind or intent of Chevron Phillips. But he is qualified to testify regarding his experience with MSDS and the scientific validity of a statement regarding the use of polypropylene in the human body.

Boston Scientific respectfully requests that this Court deny Plaintiffs’ Motion to Exclude Dr. Little’s Opinions and Testimony. The opinions Dr. Little offers in these cases are within his knowledge, skill, experience, training, and education; are based on sufficient facts and data; are derived from reliable scientific principles and methods; and will be helpful to the jury. Fed. R. Evid. 702.

### **ARGUMENT**

#### **I. Dr. Little’s Oxidative Degradation Opinions Have a Reliable Scientific Basis.**

The lynchpin of Plaintiffs’ argument is that Dr. Little has not tested explanted mesh for oxidative degradation. This Court has previously allowed biomaterials experts to testify based on their education, experience, training, and review of the pertinent scientific literature. Indeed, Plaintiffs’ own expert is permitted to testify regarding oxidative degradation based on his experience and review of the scientific literature, despite his testing being excluded as unreliable. *See Tyree v. Boston Sci. Corp.*, 54 F. Supp. 3d 501, 538 (S.D.W. Va. 2014), as amended (Oct. 29, 2014) (finding that Plaintiffs’ expert Dr. Jimmy Mays was permitted to testify regarding oxidative degradation based on his knowledge, experience, and review of scientific literature). Simply, Dr. Little’s opinions have a reliable basis without him conducting stand-alone testing.

Here, Dr. Little's report contains a lengthy review of the scientific literature, including of articles that conclude oxidative degradation occurs *in vivo*. See Exh. A at 6-13. In addition, Dr. Little's report contains over twenty footnotes to numerous pieces of literature that he considered and an additional two and a half-page reliance list of scientific literature he considered in forming his opinions. Plaintiff's contention that "Dr. Little failed to meaningfully consider the extensive body of literature in which degradation was identified by other researchers' testing and studies" is meritless on its face. Motion at 6. Indeed, Plaintiffs can only point to articles that Dr. Little not only considered but actually discussed specifically in his report. See Exh. A at 8-9 (discussing the scientific articles by *Mary* and *Clave*). As evidenced by Dr. Little's deposition, attached as Exhibit 2 to Plaintiffs' Motion, he extensively considered these studies. The fact that he considered the raw data and scientific results and formed his own conclusions shows that he meaningfully analyzed the studies in reaching his opinions. Plaintiffs can cross-examine Dr. Little regarding his interpretation of the data and any disagreements with the authors' statements or conclusions. Much like they did at deposition. Plaintiffs' true contention is not that Dr. Little did not analyze the scientific literature on degradation, but that he had analyzed the details of the data and had reached his own conclusions.

Dr. Little looked for evidence of degradation in the scientific literature and reached his opinions in his report after an intensive review of the literature, including the underlying scientific data for each study. To describe him as willfully blind ignores the hours of his deposition where he discussed the scientific literature in detail with Plaintiffs' counsel. See, e.g., Dep. at 80:19-83:5; 110:7-158:16; 205:2-211:20. His report delves into his review of the scientific literature and his background and experience with degradable and non-degradable biomaterials. It is this comprehensive review that led him to his ultimate opinions. Not an argument in a deposition of

what one picture in one study did or did not show. Combined with his education, training, and decades of experience with biomaterials, including degradable biomaterials, there is a reliable scientific basis for his opinions. Plaintiffs' motion should be denied.

## **II. Dr. Little Offers No Opinions on Chevron Phillips' State of Mind or Intent Related to the MSDS.**

Contrary to Plaintiffs' Motion, Dr. Little is not offering opinions regarding Chevron Phillips' state of mind or intent regarding the Medical Application Caution. This Court has limited expert's testimony on the MSDS only as it relates to "Chevron Phillips' state of mind or intent associated with the MSDS . . . ." *Tyree v. Boston Scientific Corp.*, No. 2:12-cv-08633, 2014 WL 5320566, at \*105 (S.D. W. Va. Oct. 17, 2014) (Goodwin, J.). Plaintiffs' attempt to exclude Dr. Little's opinions is misguided. A core purpose of expert testimony is to provide scientific and technical knowledge, including addressing the scientific validity of certain principles and theories, to assist the jury. Fed. R. Evid. 702 ("A witness who is qualified as an expert...may testify in the form of an opinion or otherwise if...the expert's scientific, technical, or other specialized knowledge will help the trier of fact to understand the evidence or to determine a fact in issue"). It is wholly within the realm of expert testimony in these cases to address whether there is scientific evidence that polypropylene should or should not be permanently implanted in the human body. Indeed, it is the center of Plaintiffs' case. If there is scientifically valid information that supports the substance of the Medical Application Caution, Plaintiffs are free to cross-examine Dr. Little with that information at trial. Moreover, Dr. Little's experience with MSDS is a proper subject of expert testimony to explain to the jury what an MSDS is and what information it contains.

## **CONCLUSION**

For all of the foregoing reasons, the Court should deny Plaintiffs' Motion to Exclude the Opinions and Testimony of Dr. Steven Little in its entirety. The opinions Dr. Little offers in these

cases are in harmony with the Court's prior Orders; are within the scope of his expertise; and are the product of a reliable scientific methodology.

Dated: February 1, 2018

Respectfully Submitted

By: /s/ Eric M. Anielak

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**CERTIFICATE OF SERVICE**

I hereby certify that on February 1, 2018, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this matter.

/s/ Eric Anielak

**COUNSEL FOR DEFENDANT  
BOSTON SCIENTIFIC  
CORPORATION**